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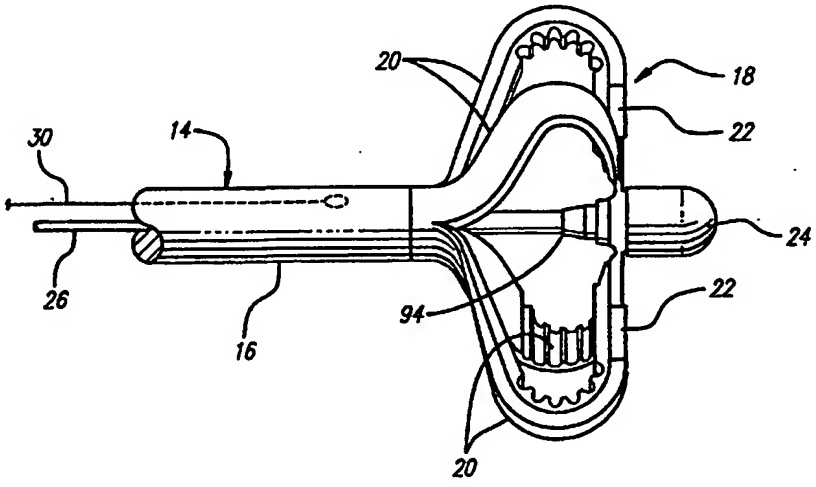

(57) Abstract

This invention is an expandable electrode array (18) mountable to the distal end of a catheter (10). The expandable array includes a plurality of adjacent elongated segments (20) preformed with proximal, medial and distal hinge portions wherein at least one electrode (22) is mounted on at least one of the segments (20). Each of the plurality of peripheral segments (20) is integrally formed with a resilient conductive longitudinal core encapsulated in an electrically insulated material. A deployment mandrel (26) is operatively connected to each of the respective peripheral segments (20) whereby movement of the mandrel (26) in the proximal direction causes the respective peripheral segments (20) to bend outwardly about the proximal, medial and distal hinge portions to radially expand the segments (20) relative to one another so that the electrodes (22) moves to a predetermined transverse coplanar orientation.

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CATHETER WITH EXPANDABLE PROBE

BACKGROUND

The invention relates generally to catheters, and more particularly, to catheters having deployable arrays.

The heart beat in a healthy human is controlled by the sinoatrial node ("S-A node") located in the wall of the right atrium. The S-A node generates electrical signal potentials that are transmitted through pathways of conductive heart tissue in the atrium to the atrioventricular node ("A-V node") which in turn transmits the electrical signals throughout the ventricle by means of the His and Purkinje conductive tissues. Improper growth of or damage to the conductive tissue in the heart can interfere with the passage of regular electrical signals from the S-A and A-V nodes. Electrical signal irregularities resulting from such interference can disturb the normal rhythm of the heart and cause an abnormal rhythmic condition referred to as cardiac arrhythmia.

Electrophysiological ablation is a procedure often successful in terminating cardiac arrhythmia. This procedure involves applying sufficient energy to the interfering tissue to ablate that tissue thus removing the irregular signal pathway. However, before an ablation procedure can be carried out, the interfering tissue must first be located.

One location technique involves an electrophysiological mapping procedure whereby the electrical signals emanating from the conductive endocardial tissues are systematically monitored and a map is created of those signals. By analyzing that map, the interfering electrical pathway can be identified. A conventional method for mapping the electrical signals from conductive heart tissue is to percutaneously introduce an electrophysiology ("EP") catheter having mapping electrodes mounted on its distal extremity. The catheter is maneuvered to place those electrodes in contact with or in close proximity to the endocardium of the patient's heart. By monitoring the electrical signals at the endocardium, aberrant conductive tissue sites responsible for the arrhythmia can be pinpointed.

Once the origination point for the arrhythmia is located in the tissue, the physician may use an ablation procedure to destroy the tissue causing the arrhythmia in an attempt to remove the electrical signal irregularities and restore normal heart beat or at least improve the heart beat. Successful ablation of the conductive tissue at

the arrhythmia initiation site usually terminates the arrhythmia or at least moderates the heart rhythm to acceptable levels.

As the EP catheter is introduced, the catheter is directed through the irregularly shaped path defined by the blood vessel and branch vessels until the distal end of the catheter reaches the heart chamber. The diameter of the catheter must be relatively small so that the catheter may be moved through the relatively small diameter blood vessels to the heart. Once the distal end of the catheter is at the desired location within the heart, EP mapping and ablation procedures may commence.

It has been found that if a plurality of mapping electrodes are located in a spaced-apart planar grid, the electrical signals emanating from the endocardium of the heart may be more efficiently and accurately mapped using vector analysis to pinpoint arrhythmias. However, such a configuration increases the size of the catheter substantially and inhibits percutaneous introduction of the catheter through the vascular system. Therefore, some EP catheters are provided with an expandable/collapsible electrode array located at their distal ends. Once positioned within the intracardial volume of the heart, the array can be deployed wherein the mapping electrodes are positioned so that they are spaced outwardly relative to one another in the planar-type array.

To expand the electrode array to its completely deployed state, a deployment mandrel is located in the catheter lumen, connected at its distal end to the electrode array, and connected at its proximal end to a deployment control device. The deployment control device is included in a catheter manipulation handle at the proximal end of the catheter tube. The deployment control device may be manually operated to pull the mandrel and the center of the array in a proximal direction relative to the catheter tube to expand the electrode array to its fully deployed position at the end of the catheter. The catheter may then be used for the mapping/ablation procedure.

To maneuver the deployed array as desired to reach target tissue, the steerable catheter may incorporate a deflection control line to control the deflection of the distal tip. Pulling the proximal end of the control line at the manipulation handle causes the distal tip of the catheter to deflect in one direction so that the tip may be

directed through selected blood vessels or put into the desired location in the heart. Such a system is shown in U.S. Patent 5,364.352 to Cimino et al.

Once the EP catheter has been directed to the heart, the deployment mandrel may be pulled to deploy the electrode array. The deflection control line may be then operated to adjust the curvature at the end of the catheter to direct or steer the electrode array toward selected tissue sites. The curvature and position of the distal end of the catheter may have to be finely adjusted many times in order to properly position the array for complete and comprehensive monitoring of the electrical signals emanating from the conductive heart tissue to effectively map and detect arrhythmatic points of origin.

One such catheter having an expandable electrode array is disclosed in U.S. Patent No. 4,940,064 to Desai. While the catheter and expandable array disclosed have provided a significant advance in the art, a more easily manufacturable array is desirable.

Once in the heart chamber, expandable electrode arrays having a plurality of electrodes may be required to expand and collapse many times during EP procedures. It is important for accuracy that each electrode assume a known position in relation to other electrodes at each deployment; i. e., coplanar and orthogonal. Thus a stable structure is desirable as well as a structure robust enough to undergo multiple deployments and collapsing without breakage. Additionally, repeatability between different catheter arrays is desirable so that the electrodes of one array are in the same relative positions as those of the next.

Furthermore, electrode leads and connections of those leads to the array electrodes should be well insulated so as to not expose the patient to electrical energy other than at the exposed electrodes. Additionally, the electrode leads and connecting must be robust enough to withstand repeated bending and elevated temperatures should an ablation procedure be undertaken.

Hence, those skilled in the art have recognized the need for a catheter that includes an expandable distal end for providing a planar array of electrodes for EP procedures. Such an array must assume a known shape during repeated *in vivo* deployments and be robust enough to withstand the deflections that occur in reaching the target tissue and in relocations to different target tissue. Additionally, the need has been recognized for an array that is relatively simple to manufacture

and that can be manufactured repeatably. The present invention fulfills these needs and others.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is directed to a catheter having an expandable array at its distal end comprising a plurality of elongated peripheral segments, each of the segments having a plurality of pre-formed hinges, at least one electrode mounted on at least one of the segments, and a deployment mandrel operatively connected to control the deployment of the segments. In a further aspect, movement of the mandrel in the proximal direction causes the respective peripheral segments to deploy outwardly about the pre-formed hinges. In a further aspect, the hinges comprise proximal, medial, and distal hinge portions and the deployed segments bend about the medial hinge portions, radially expanding the segments relative to one another about the medial hinge portions so that the electrode moves to a predetermined orientation.

In another aspect, the catheter further includes an electrode at the distal tip of the body member with the mandrel electrically conductive and fastened to that electrode.

In a further aspect, a frame of conductive material includes a plurality of elongated core members having inner and outer ends, the respective inner ends of the core members spaced a predetermined distance apart and joined by removable tabs, the outer ends of the core members diverging outwardly from one another to join the frame. The core members are encapsulated with an electrically insulative material to define segments and forming an electrically insulative central portion between the inner ends of the core members. Hinges having a reduced cross sectional dimension of the insulative material are formed at selected positions on the segments. At a medial position, a longer hinge is formed. The frame and connecting tabs are removable to leave an expandable array.

Other aspects and advantages of the invention will become apparent from the following detailed description and accompanying drawings, illustrating by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a side view of an electrophysiological catheter embodying features of the invention, and illustrating the distal end thereof having an expandable electrode array in a collapsed or unexpanded configuration;

FIG. 2 is a side view of the distal portion of the electrophysiological catheter shown in FIG. 1 illustrating the expandable electrode array in its expanded configuration;

FIG. 3 is a side view of the distal portion of the electrophysiological catheter shown in FIG. 2 illustrating the expanded electrode array with the distal end of the catheter in a deflected configuration;

FIG. 4 is an enlarged partial sectional side view of the distal portion of the catheter shown in FIG. 1;

FIG. 5 is a partial sectional side view of the distal portion of the catheter shown in FIG. 2;

FIG. 6 is a top view of a metallic frame used during fabrication of the expandable array including a plurality of core members of the expandable array;

FIG. 7 is an enlarged broken view of a portion of the core members of the array shown in FIG. 6;

FIG. 8 is a enlarged bottom view of the core members of the array encapsulated in polymeric casings and trimmed from the frame shown in FIG. 6 to form a plurality of array segments;

FIG. 9 is an enlarged, partially broken, sectional and rotated side view of the array of FIG. 8;

FIG. 10 is an enlarged cross sectional view of one segment of the array taken along lines 10-10 of FIG. 9, and depicting a sensing electrode mounted thereon in one configuration;

FIG. 10A is an enlarged cross sectional view of one segment, similar to that shown in FIG. 10, but illustrating the sensing electrode having a different shape;

FIG. 11 is an enlarged cross sectional view of one segment of the array taken along lines 11-11 of FIG. 9;

FIG. 12 is a partially sectional side view of the manipulation handle shown in FIG. 1, including an array deployment control device in a distal position to collapse the array, and including a deflection control device in its non-operative position (catheter not deflected); and further including a displacement compensation device;

FIG. 13 is partially sectional side view of the manipulation handle shown in FIG. 12 illustrating the array deployment control device in its operative position to expand the array, and showing the deflection control device in its operative position to deflect the distal end of the catheter;

FIG. 14 is an exploded perspective view, partially in section, of the manipulation handle shown in FIGS. 12 and 13;

FIG. 15 is an enlarged side view of the displacement compensation device shown in FIGS. 12 and 13;

FIG. 16 is an side view, partially in section, of the displacement compensation device shown in FIG. 17; and

FIG. 17 is an end view of the displacement compensation device shown in FIGS. 15 and 16.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

In the following description, like reference numerals will be used to designate like or corresponding elements among the several figures of the drawings. Referring now to the drawings and particularly to FIGURE 1 there is shown a catheter 10 usable for electrophysiological procedures and embodying features of the invention. Briefly, the catheter 10 includes a manipulation handle 12, an elongated catheter shaft or body member 14, an expandable electrode array 18 located at the distal end 16, a deployment control device 26, and a body member deflection control device 30.

The expandable electrode array 18 includes a plurality of peripheral elongated segments 20 with each segment including an exposed electrode 22 on its exterior, and a generally hemispherical tip electrode 24 at the distal tip of the array 18. The body member 14 has an inner lumen (not shown) that extends to the distal tip and that has disposed therein a plurality of electrical conductors that are electrically connected to the electrodes 22. In addition, the deployment control device 26 is slidably disposed within the inner lumen of the catheter body member 14 and preferably comprises an electrically conductive deployment mandrel 26 having its distal end not only electrically connected but also mechanically fastened to the tip electrode 24.

The plurality of distal end segments 20 are flexible and resilient and configured in a substantially straight shape so that when bending forces are imparted to the segments, the inherent restoring forces of the material itself tend to straighten the segments to their straight or unbent position when the bending forces have been

removed. The deployment mandrel 26 is used to impart such bending forces counteracting the segments' inherent restoring forces. The mandrel 26 has axial rigidity so that it can not only be pulled but also pushed to control the deployment of the expandable electrode array 18 at the distal end 16 of the body member 14. Pulling the mandrel 26 deploys the array 18 and pushing the mandrel collapses the array.

Referring now additionally to FIGS. 2 and 3, the distal tip of the deployment mandrel 26 is attached to the proximal end of the tip electrode 24. Proximal movement of the deployment mandrel 26 will cause the tip electrode to be moved proximally. Because it is mounted on the array segments 20, the segments are forced to move out of the way of the tip electrode. They do so by bending outwardly as shown in FIGS. 2 and 3. The tip electrode can then be pulled into contact with a stop surface 94 at the distal end 16 of the body member 14 of the catheter and into the deployed/expanded position. This creates the planar array of electrodes 22 shown in FIGS. 2 and 3.

Moving the mandrel 26 distally has the opposite effect. The tip electrode 24 is moved distally as are the array segments 20 connected to the electrode 24 and they collapse onto the body member 14 in the straight shape shown in FIG. 1.

The body member deflection control device 30 is also disposed within the catheter body member 14 and has its distal end attached at the distal end 16 of the body member. The deflection control device preferably comprises a deflection control line 30 having a lubricous coating or jacket (not shown). Pulling the deflection control line 30 will cause a deflection of the distal end 16 of the catheter body member 14. The body member 14 is fabricated of a flexible, resilient material constructed in substantially a straight shape so that when a bending force is imparted to the body member, an opposing straightening or restoring force originating from the body member itself tends to oppose the bending force. When the bending forces have been removed, the inherent material straightening forces tend to return the body member to its straight shape. The deflection control line 30 is used to impart such deflection forces to overcome the body member's restoring force and hold the distal end in a deflected position.

The distal tip of the deflection line 30 is affixed by brazing, soldering, or similar means to an anchor band 32 (FIG. 3) mounted in the distal end 16 of the

catheter body member 14. The control line is disposed within another lumen formed in the catheter body member 14 so as to be off-set from the central longitudinal axis of the catheter body member to more easily effect the controlled deflection of the flexible distal end 16.

When the expandable electrode array 18 is in its collapsed state, as shown in FIG. 1, sliding movements of the control element 28 operate on the deflection control line 30 to result in selective deflection of the catheter distal end for steering the body member 14. The catheter may be steered so that the body member carrying the electrode array 18 may be positioned at desired locations in a patient's intracardial volume of the heart. Once within the intracardial volume of the heart, the electrode array may be deployed, and the deflection control line 30 controlled to allow the physician to adjust the deflection of the distal end 16 of the catheter 10 for placement of the electrodes against target tissue. The electrodes 22 as well as the tip electrode 24 may be used both for mapping and ablation.

The deployment mandrel 26 and the deflection control line 30 are preferably formed of a stainless steel suitable for *in vivo* use, although other materials may be used. The deflection line 30 in one embodiment was about 0.127 to about 0.254 mm (0.005 to 0.010 inch) in diameter and the deployment mandrel 26 was about 0.254 to about 0.508 mm (0.010 to 0.020 inch) in diameter, and the lengths thereof are appropriate for the catheter in which they are utilized. The above sizes would be adjusted for catheters of different sizes.

Referring now to FIGS. 4 and 5, the expandable electrode array 18 in this embodiment includes four peripheral segments 20. For purposes of illustration and clarity, only two segments are shown. Briefly and in general terms, each of the segments 20 includes a flexible resilient, electrically conductive metallic core member 34 encapsulated in a polymeric electrically insulative casing 36. Each of the respective segments is formed with distal, medial, and proximal pre-formed hinge portions, 38, 40 and 42 respectively, such that when the deployment mandrel 26 is retracted, the segments 20 bend at predetermined places and in predetermined orientations at the respective hinge portions to result in the electrodes 22 expanding outwardly to a predetermined configuration.

Referring now to FIGS. 6 through 12, the method of manufacturing the expandable electrode array 18, and the construction of the electrode array itself will

be described in detail. To manufacture the expandable electrode array, a thin sheet of electrically conductive resilient material (not shown), of a thickness on the order of 0.05 mm (0.002 in.) is selected. In the preferred embodiment, the sheet is composed of a nickel-titanium alloy that provides desired flexibility, resilience, strength, and electrical conductivity. In the alternative, stainless steel may be utilized. The sheet is produced using photo-lithography, photo-etching, or other techniques to provide the configuration shown in FIG. 6. As shown, the sheet exhibits a generally square peripheral frame 44 having a generally cruciform blank 46 attached within it, the legs thereof forming the respective core member 34 of each array segment 20, each core member having an inner and an outer end 48 and 50 respectively.

Referring more particularly to FIG. 7, the respective inner ends 48 of the respective core members 34 are attached together by right angle tabs 52 having perforations 53 used later in removing the tabs at designated points. The tabs provide spacing between the inner ends of the core members and provide structural integrity to the blank 46 during the manufacturing process. The inner ends of the core members are spaced a predetermined distance apart.

Additionally, the distal end of each core member 34 includes two flow-through holes 55 through which the encapsulant material will flow to provide a stronger bond of the encapsulant to the core members. Furthermore, three slots 57 are shown that also assist in creating a stronger bond of the encapsulant material to the core members. Under high heat conditions, such as those that exist when ablating tissue, these flow-through holes 55 and distal tip slots 57 lessen the chances of delamination of the encapsulant material from the core members.

Referring to FIG. 8, the bottom side of the blank 46 is shown in which the core members 34 have been encapsulated in a polymeric casing 36 utilizing injection molding or over-molding processes known well to those skilled in the art. The casing material is electrically insulative. The casings 36 are of uniform width along the length of the respective core members. The central portion of the blank 46, between the inner ends 48 of the core members 34, is molded and filled with polymeric material to form a generally square central electrode mounting plate 64, the mounting plate formed with a central axial through bore 66.

The blank 46 is trimmed from the frame 44 at the respective outer ends 50 (FIGS. 6 and 7), and the respective tabs 52 are trimmed from the inner ends 48 of the respective core members 34 to form the generally cruciform configuration shown in FIG. 8, the legs thereof defining the segments 20 of the expandable electrode array 18. Because the tabs 52 were broken away, none of the respective core members 34 are in electrical contact with any other so that the core members are electrically isolated from one another. The surface of the electrodes 22 may then be cleaned or ground to assure that no polymeric material remains over them. In addition, the electrodes 22 may be ground to assure a smooth finish so that no sharp edges exist that may cause trauma to tissues.

With particular reference to FIG. 9, the mounting plate 64 is relatively thin with respect to the thickness of the casings 36 of the segments 20. In addition, the bottom surface at the inner ends 48 of the respective casings are formed with clearance tapers 68, tapering upwardly and inwardly to the mounting plate to avoid any interference when the segments are bent to the shape shown in FIG. 4.

As illustrated in FIGS. 8 and 9, the bottom sides of the respective casings 36 are formed with a plurality of transverse slots. The slots in one embodiment are molded into the plastic and located at selected distances along the length of the respective segments 20. The slots provide predetermined bending areas or hinges at which the array will bend when deployed or collapsed, depending on the hinge. A first transverse slot 70 defining the distal hinge portion 38 is located at the bottom surface of each casing 36, at the inner end 48 thereof, and inside of the inner extremities of the core members 34 and generally at the periphery of the central mounting plate 64. Spaced a predetermined distance outwardly from the first transverse slot are a plurality of adjacent second transverse slots 72 defining the medial hinge portion 40. In one embodiment, the number of second slots 72 comprising the medial hinge portion is six, however more or fewer slots may be used depending on the arc of curvature desired. Spaced a predetermined distance outwardly from the outward-most slot of the set of second transverse slots is a third transverse slot 74 defining the proximal hinge portion 42.

With particular reference to FIGS. 10 through 11, the cross sectional configuration of the respective segments 20 is described in detail. As shown, the cross section of each of the respective casings 36 of the segments 20 is generally in

the form of a circular quadrant having a rounded upper surface 76 and downwardly converging side walls 78. The bottom of the casing is formed with an inwardly rounded bottom surface 80 concentric with the rounded upper surface. The electrodes 22 have a generally rectangular cross-sectional shape with smooth rounded corners at the upper surface. As shown in FIG. 10, the planar upper surface of the electrode is positioned in a tangential orientation relative to the upper rounded surface 76 of the casing such that the rounded corners of the electrode project from the casing to a minor degree. Alternatively, as shown in FIG. 10A, the electrodes may be formed or ground down to have a rounded contoured upper surface, shaped in conformity with the rounded upper surface 76 of the respective segments. The contoured surface eliminates the protrusion of any surface beyond the rounded upper surface 76 of the respective segments such that when the array is in its collapsed state, a smoother surface and smaller profile exist.

As shown in FIG. 11, a transverse slot 72 of the casing 36 traverses the bottom portion of the casing, but does not disturb the integrity of the casing's encapsulation of the core member 34.

Returning to FIGS. 4 and 5, the catheter body member 14 and the mounting and assembly of the expandable electrode array 18 onto the distal end 16 thereof is described hereinafter in detail. As shown, the catheter body member 14 includes an inner lumen 82 formed along the central axis thereof extending the length of the body member and the distal extremity of the catheter body member is formed with a tapered countersink 84.

With particular reference to FIG. 4, the distal tip electrode 24 is generally of a bullet shape having a hemispherical nose. The proximal end of the tip electrode 24 includes a projecting mounting stem 86 having an axial bore 88 for receipt of the distal tip of the deployment mandrel 26, the mandrel being affixed therein by crimping, soldering, brazing or other means. When assembled, the stem of the tip electrode 24 is passed through the central bore 66 of the mounting plate 64 so that the stem and mandrel project proximally from the bottom side thereof. A retaining hub 90 is slid over the proximal end of the mandrel and adhesively bonded to the mounting stem sandwiching the mounting plate 66 between the back surface of the tip electrode and the retaining hub 90 to securely affix the tip electrode mounting plate of the expandable array 18. In an alternative embodiment, the tip electrode 24

may be formed with a peripheral slot, held within the frame 44 (FIG. 6), and the polymeric casing molded around it to engage the peripheral slot thereby holding the tip electrode 24 in a fixed position.

A first tubular sheath 92 is provided having a predetermined length and outer diameter, the distal tip thereof defining a stop surface 94. The first sheath 92 has an inner diameter sized for slidable receipt of the deployment mandrel 26. Because the first sheath 92 and the mandrel 26 are coaxial, the stop surface is in confronting relationship with the retaining hub 90 of the tip electrode 24. A pair of small-diameter sealing O-rings 96 having an inner diameter sized for snug receipt of the mandrel are mounted over the mandrel to abut the proximal end of the first sheath and prevent the passage of fluids.

A flexible elongated second tubular sheath 98 is provided proximal to the first sheath 92 and has a similar outer diameter as the first sheath 92. Furthermore, it has a length substantially the length of the catheter body member 14. The outer diameter of the second sheath is sized for receipt within the inner lumen 82 of the body member 14 and the inner diameter sized for sliding receipt of the mandrel 26. The second sheath is mounted over the mandrel 26 to abut the O rings 96. The distal extremity of the first sheath is a predetermined distance from the retaining hub 90 of the tip electrode 24. The second sheath is composed of PTFE which provides sufficient lubricity such that the mandrel may slide therein without undue frictional constraint. The first sheath is composed of polyimide which provides sufficient rigidity to resist buckling when confronting the retaining hub during deployments of the array.

When the expandable electrode array 18 is assembled, the first sheath 92, O-rings 96 and second sheath 98 are spaced on the deployment mandrel 26 a predetermined proximal distance from the proximal surface of the mounting plate 66. The plastic molding at the proximal and inside portions of the legs 36 is stripped off to expose the underlying electrical conductor 34. Electrical leads are attached to the inside surfaces of the legs and the legs are folded closed over a spacing mandrel (not shown). The legs are then all heat melted together, or an appropriate adhesive may be applied to connect them together permanently in the shape provided by the spacing mandrel between the third slots 74 and the outer ends 50 thereof (FIG. 8). The segments are then heat melted to the distal end of the second sheath 98, the O

rings 96, and the proximal end of the first sheath 92. In the alternative, an adhesive may be applied to bond the fused segments to the first and second sheaths 92 and 98 respectively. However, the distal portion of the first sheath 92, distal to the third slot 74, is not bonded to the respective outer ends of the segments. As shown, the clearance tapers 98 of the respective segments provide clearance for the retaining hub 90 of the tip electrode 24 when the array is in its collapsed state. Also, the segments 20 clear the first sheath 92 because of their inwardly rounded bottom surfaces 80 (FIG. 10).

The array is hot melted to the distal end of the body member 14 in order to attach it. In one embodiment, a section of similar material can be used as a filler 100 within the joint section.

As shown in FIGS. 1 and 4, when the electrode array is in its collapsed state, the diameter of the array is substantially the same diameter as the outer diameter of the catheter body member 14. The deployment mandrel 26 is free to slide within the first and second sheaths 92 and 98 to expand and collapse the electrode array 18, while the O-rings 96 seal the mandrel so that bodily fluids do not enter the inner lumen 82 of the body member 14.

Referring to FIG. 5, the deployment mandrel 26 may be pulled proximally relative to the distal end 16 of the body member 14, whereby the distal tip of the mandrel pulls the tip electrode 24 in the proximal direction. As shown, the peripheral segments 20 bend at the distal, medial and proximal hinge portions 38, 40 and 42. The gradual bending at the medial hinge portion 40 due to a plurality of slots 72 prevents the conductive core member 34 from being bent too sharply or at an angle such that the encapsulated core member could break disrupting electrical continuity to the electrode 22. The portions of the segments between the distal and medial hinge portions resist bending due to the relative large width of the mounting pads 48 and the rigidity of the electrodes 22 mounted thereon. The proximal hinge portions 42 bend along the third transverse slots 74 relatively easy with limited bending resistance because the polymeric material of the casing is relatively thin.

With continued reference to FIG. 5, the deployment mandrel 26 may be pulled proximally far enough such that the retaining hub 90 of the tip electrode 24 contacts the stop surface 94 at the distal end of the first sheath 92. The stop surface is positioned at a predetermined distance from the retaining hub in the collapsed

configuration such that when the retaining hub contacts the stop surface, the forward portions of the respective segments 20 move radially outwardly about the hinge to an extent where the forward portions are disposed in a generally transverse planar orientation relative to one another. When the forward portions are at such orientation, the electrodes 22 are oriented so that they are all forward facing. When in such configuration, the electrodes may more effectively sense electrical signals emanating from the endocardium of the heart and more effectively make contact with the heart tissue to apply ablation energy. Electrical signals are conducted by the respective conductive core members 34 and through the sensor leads (not shown) disposed within the inner lumen 82 of the body member 14 and to a connector (not shown) mounted in the manipulation handle 12. The external electrical connector 18 (FIG. 1) is connected to signal analysis equipment which provide electrical signal data indications to the physician as well as ablation energy.

The stop surface 94 prevents the deployment mandrel 26 from being retracted within the sheaths 92 and 98 any further which in turn assures that the array 18 is deployed in its predetermined planar orientation while preventing the array from being over-deployed. Deployment of the array at an orientation other than the predetermined orientation may cause irregular electrode sensing characteristics. In addition, over-deployment may cause damage to the internal components of the electrode array.

With particular reference to FIGS. 12, 13 and 14, the manipulation handle 12 will be described in greater detail. The handle 12 includes a handle body 110 formed with an elongated hollow cylindrical sleeve 112 having a contoured cap 116 affixed to proximal end of the handle body. The contoured cap 116 includes an electrical connector (not shown) for conducting electrical signals to and from the catheter. The electrical connector may be connected to a complementary plug 118 of an external cable, as shown in FIG. 1, that may be connected to instrumentation.

An elongated generally hollow nut element 132 is provided for rotational movement in response to the operator's rotation of a control element 28. Rotational movement of the nut element 132 causes longitudinal movement of a screw element 154 mounted within the nut element. The mandrel 26 is mounted to the screw element so that movement of the screw element causes longitudinal movement of the mandrel. A deployment control system is included in the handle shown that

compensates for deflection of the distal end of the catheter and for over-rotation of the control element 28. For further details of the deployment control system, see the U.S. patent application entitled "Catheter Control System" to Rusk et al. filed the same day as the present application, having docket no. 36202 and incorporated herein by reference.

The proximal end of the mandrel 26 is connected to an electrically conductive jumper wire 180 that completes the electrical path from the tip electrode through the mandrel to the internal connector.

With particular reference to FIGS. 12 and 13, the operation and control of the expandable electrode array will be described in detail. To control the deployment mandrel 26, the control element 28 may be rotated relative to the handle body 110 causing rotation of the nut element 132. As the control element 28 is rotated, the screw element 154 is driven longitudinally by the nut element along the tubular shaft 122 moving the mandrel with it. As shown in FIG. 12, the control element 28 has been rotated such that the screw element 154 is disposed in the distal end of the female element 132. In this position, the mandrel has been moved distally to collapse the electrode array 18, as shown in FIG. 1.

To expand the array to its deployed configuration, the control element 28 is rotated relative to the handle body 110 such that the screw element 154 is drawn in the proximal direction within the nut element 132, as shown in FIG. 13, resulting in longitudinal movement of the deployment mandrel 26 within the catheter body member 14. Consequently, the deployment mandrel 26 pulls the tip electrode 24 proximally to flare the respective segments 20 radially outwardly, as shown in FIG. 2, until the mounting nut 90 abuts the stop surface 94 of the array.

Referring to FIGS. 12, 13, and 14, the operation of the deflection control device of the catheter 10 is described in detail. The deflection of the distal end is controlled by the control element 28 that slides to achieve such deflections. As shown in FIG. 12, the control element 28 has been slid to its distal position wherein the control line applies no tensile force to the distal end 16 of the body member and thus the catheter would be disposed in its undeflected state as shown in FIG. 1.

As shown in FIG. 13, the control element 28 has been slid to its proximal position. With the control element in this position, the control line has exerted tension on the distal end 16 of the catheter body member 14 deflecting it as shown in

FIG. 3. A pulley mechanism 26 is also included in conjunction with the deflection control device. For further details, see co-pending patent application entitled "Catheter Control System Having A Pulley" by Thornton, et al. filed this same day and incorporated herein by reference.

Once the distal end deflection of the body member 14 has been selected, the clinician may release the control element 28 and it will remain in the position selected due to the inclusion in the handle of a locking device. The locking device 142 in this embodiment exerts an outward radial force to impart a continuous locking force against the control element bore 168 greater than the tensile force of the deflection control line 30. For further details on a locking device incorporating the above feature, see the patent application filed the same day as this application entitled "Locking Mechanism For Catheters" to Iain Smith and incorporated herein by reference.

The displacement compensation device 157 of the invention applies a biasing force between the mandrel and the screw element 154 to assure the desired position of the deployed or collapsed array. With reference to FIG. 15, a first spring biases the mandrel in the proximal direction and a second spring biases the mandrel in the distal direction. For further details of such a displacement compensation device 157, see the Catheter Control System" application incorporated herein previously.

While the invention has been described herein in terms of certain embodiments, it is clear that the embodiment are susceptible to numerous modifications and adaptations within the ability of those skilled in the art and without the exercise of inventive faculty. Thus, it should be understood that various changes in form, detail and usage of the present invention may be made without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An expandable electrode array mountable to the distal end of a catheter comprising:

a plurality of peripheral segments, each of the segments having a plurality of pre-formed hinges;

at least one electrode mounted on at least one of the segments; and

a deployment mandrel disposed between the segments and operatively connected to each of the respective peripheral segments;

whereby movement of the mandrel in the proximal direction causes each peripheral segment to bend outwardly about the respective pre-formed hinges so that the respective electrode moves to a predetermined orientation.

2. An expandable electrode array mountable to the distal end of a catheter comprising:

a plurality of elongated peripheral segments, each of the segments formed with a proximal, medial and distal hinge portion, each medial hinge portion dividing the segments into respective substantially rigid proximal and distal end portions, the respective distal hinge portions mounted at a predetermined orientation relative to one another and the proximal hinge portions mounted at a predetermined orientation relative to one another and movable in an axial direction;

at least one electrode mounted on at least one of the distal end portions of the segments; and

a deployment mandrel concentrically oriented within the segments, the distal end of the mandrel operatively connected to the distal hinge portions of the respective peripheral segments;

whereby movement of the mandrel in the proximal direction relative to the proximal hinge portions causes the proximal end portions to pivot radially outwardly about the proximal hinge portions and the distal end portions of the respective peripheral segments to pivot radially outwardly about the distal hinge portions and medial hinge portions so that each of the respective distal portions tend to move to a predetermined transverse coplanar orientation relative to one another.

3. A catheter having an expandable distal end, the catheter comprising:

a body member having a distal end and a proximal end;

a plurality of elongated resilient peripheral segments at the distal end of the body member, the segments having a restoring force tending to maintain the segments in a predetermined shape, each of the segments formed with a proximal, medial and distal end hinge portions, each medial hinge portion dividing the segments into respective substantially rigid proximal and distal end portions;

a manipulation handle attached to the proximal end of the body member having a movable first element;

a deployment mandrel mounted in the body member connected at a proximal end to the first element of the handle and extending to the distal end of the body member, the distal tip of the mandrel connected to the respective peripheral segments whereby movement of the first element in a proximal direction causes the proximal end portions to pivot radially outwardly about the proximal hinge portions and causes the distal end portions of the respective peripheral segments to move in a proximal direction pivoting radially outwardly about the distal hinge portions and medial hinge portions so that each of the respective distal portions tend to move to a predetermined transverse coplanar orientation relative to one another.

4. The catheter of claim 3 wherein the catheter further includes:

an ablation electrode at the distal tip of the body member and the mandrel is electrically conductive, the distal end of the mandrel connected to the tip electrode.

5. The catheter of claim 3 wherein:

each of the plurality of peripheral segments is integrally formed with a resilient conductive longitudinal core configured to maintain the segments in an undeployed position under the resiliency of the core.

6. The catheter of claim 3 wherein:

each of the peripheral segments includes a respective electrode positioned on the distal portion thereof and is in contact with the conductive core; and

each respective conductive core is connected to an electrical lead passing through the body member to the handle.

7. The method of fabricating an expandable electrode array mountable to the distal end of a catheter, comprising the steps of:

selecting a sheet of electrically conductive resilient material;

stamping the sheet to form a peripheral frame and a plurality of elongated core members having inner and outer ends, the respective inner ends of the core members spaced a predetermined distance apart and joined by tabs, the outer ends of the core members diverging outwardly from one another to join the frame;

encapsulating the core members and tabs in an electrically insulative material to define segments and forming an electrically insulative central portion between the inner ends of the core members;

forming respective distal hinge portions by altering the cross sectional dimension of the insulative material at the inner ends of the segments;

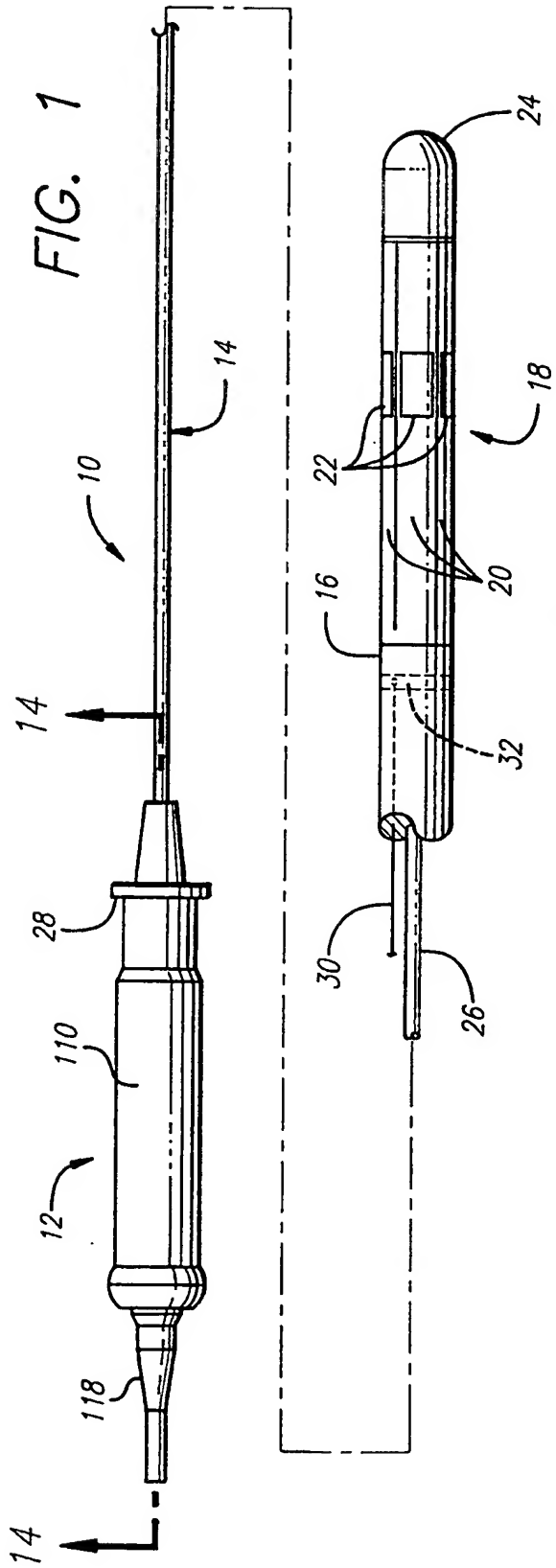
forming respective medial hinge portions by altering the cross sectional dimension of the insulative material between the inner end and outer end of the segments;

forming respective proximal hinge portions by altering the cross sectional dimension of the insulative material at the outer ends of the segments;

trimming the outer ends of the core members from the peripheral frame; and

trimming the tabs from the inner ends of the core members leaving the central portion intact.

FIG. 1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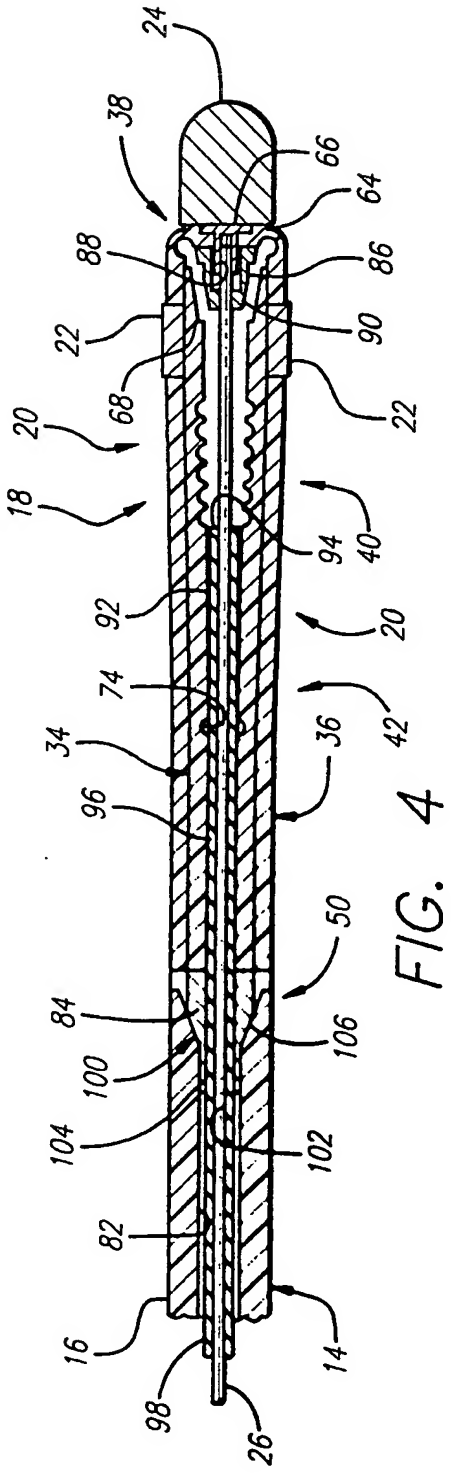
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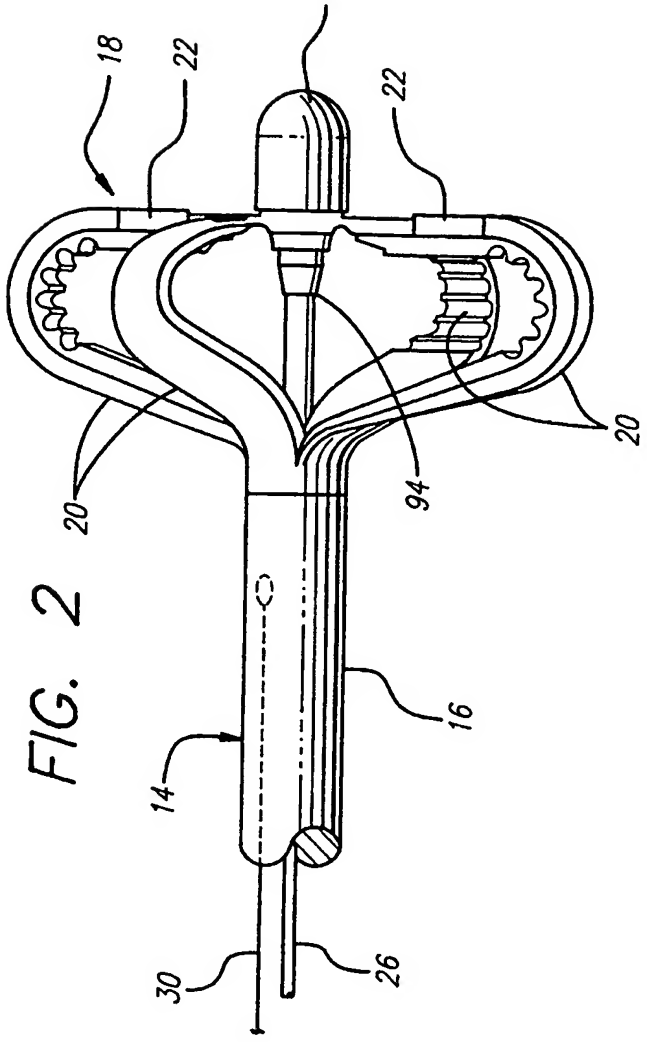
FIG. 4

FIG. 2



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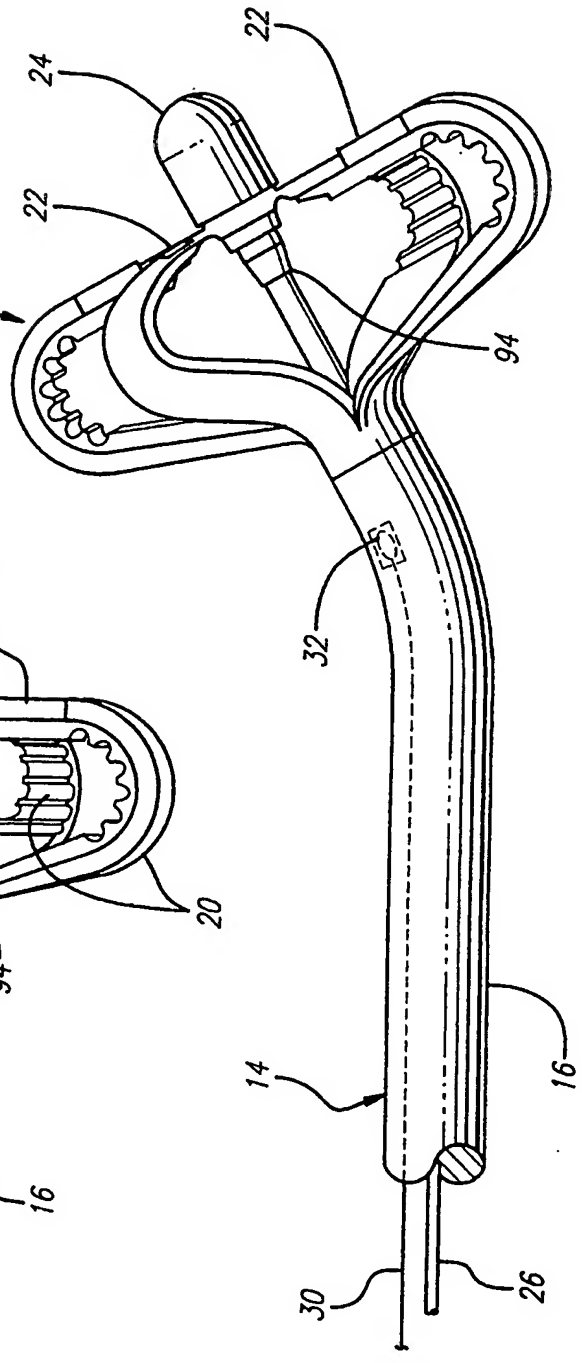

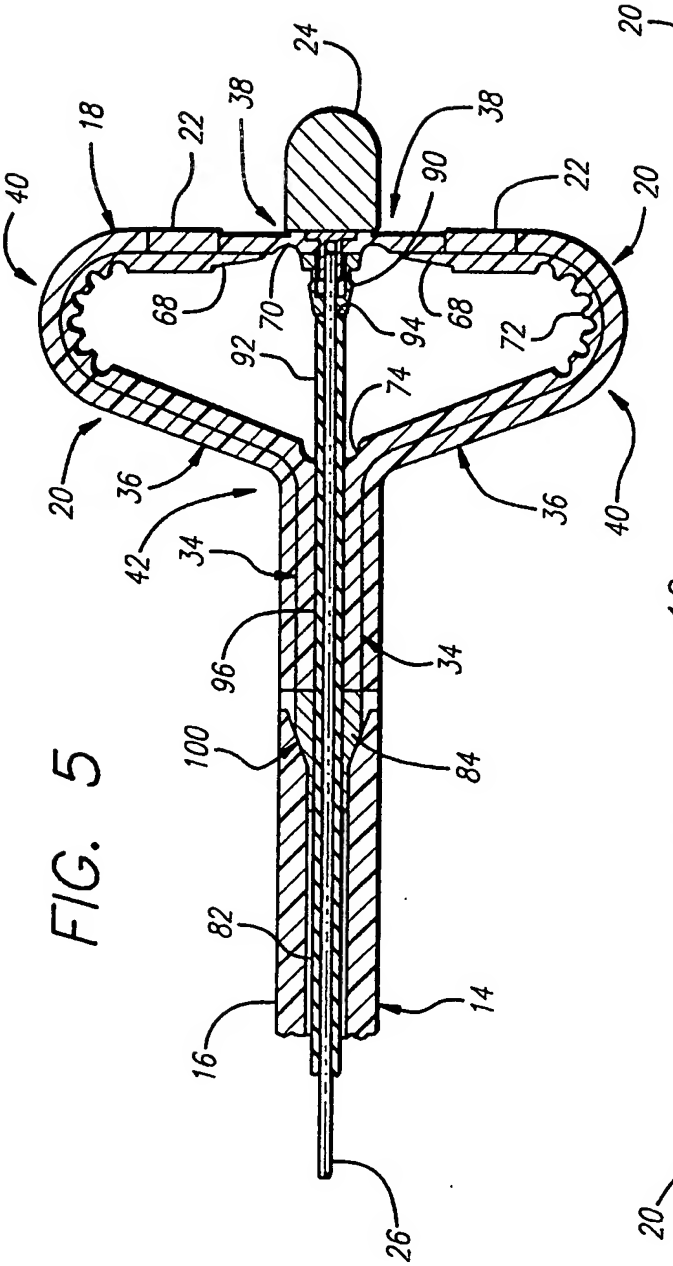
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FIG. 5

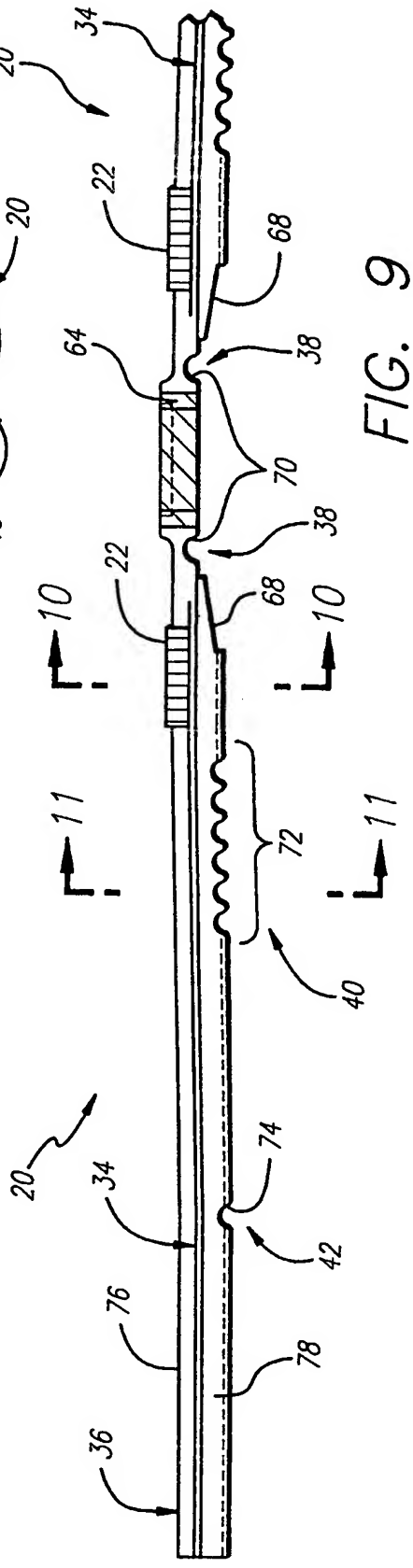
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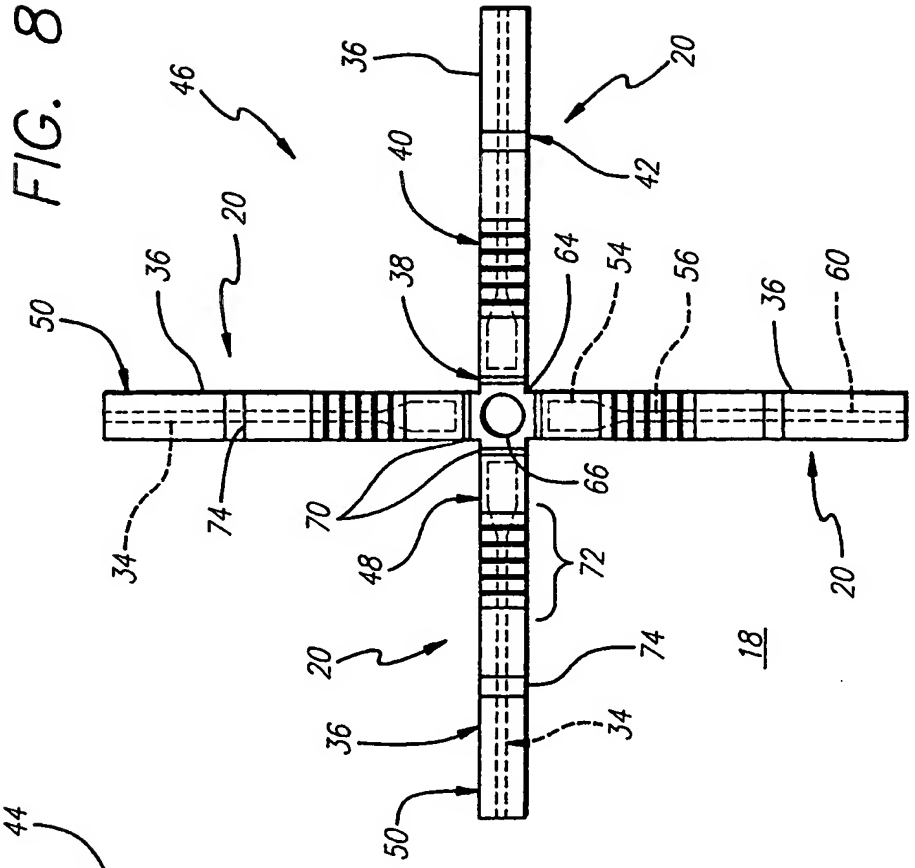
FIG. 9

FIG. 8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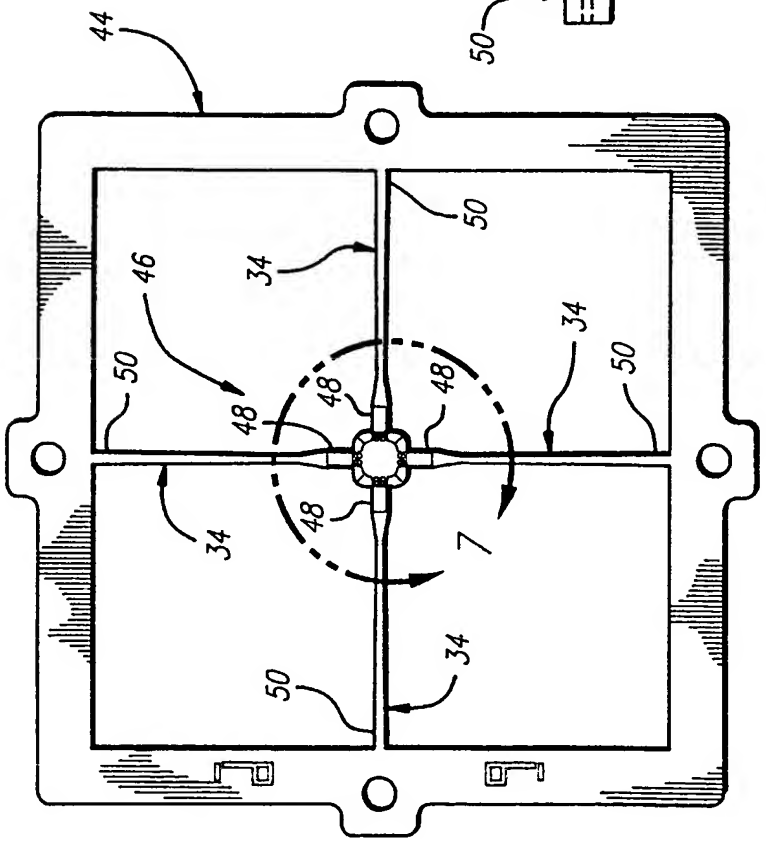
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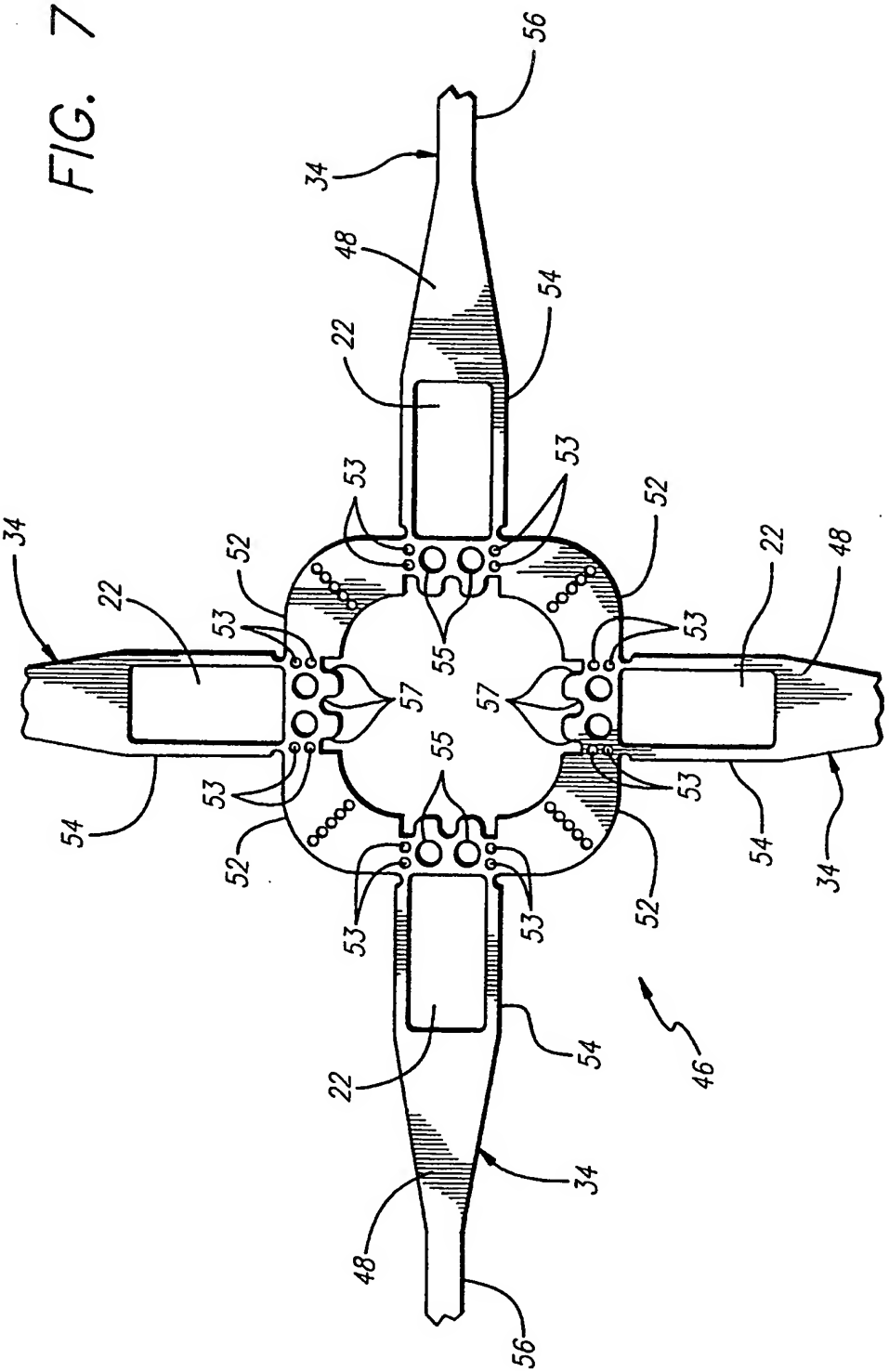
FIG. 6

FIG. 7



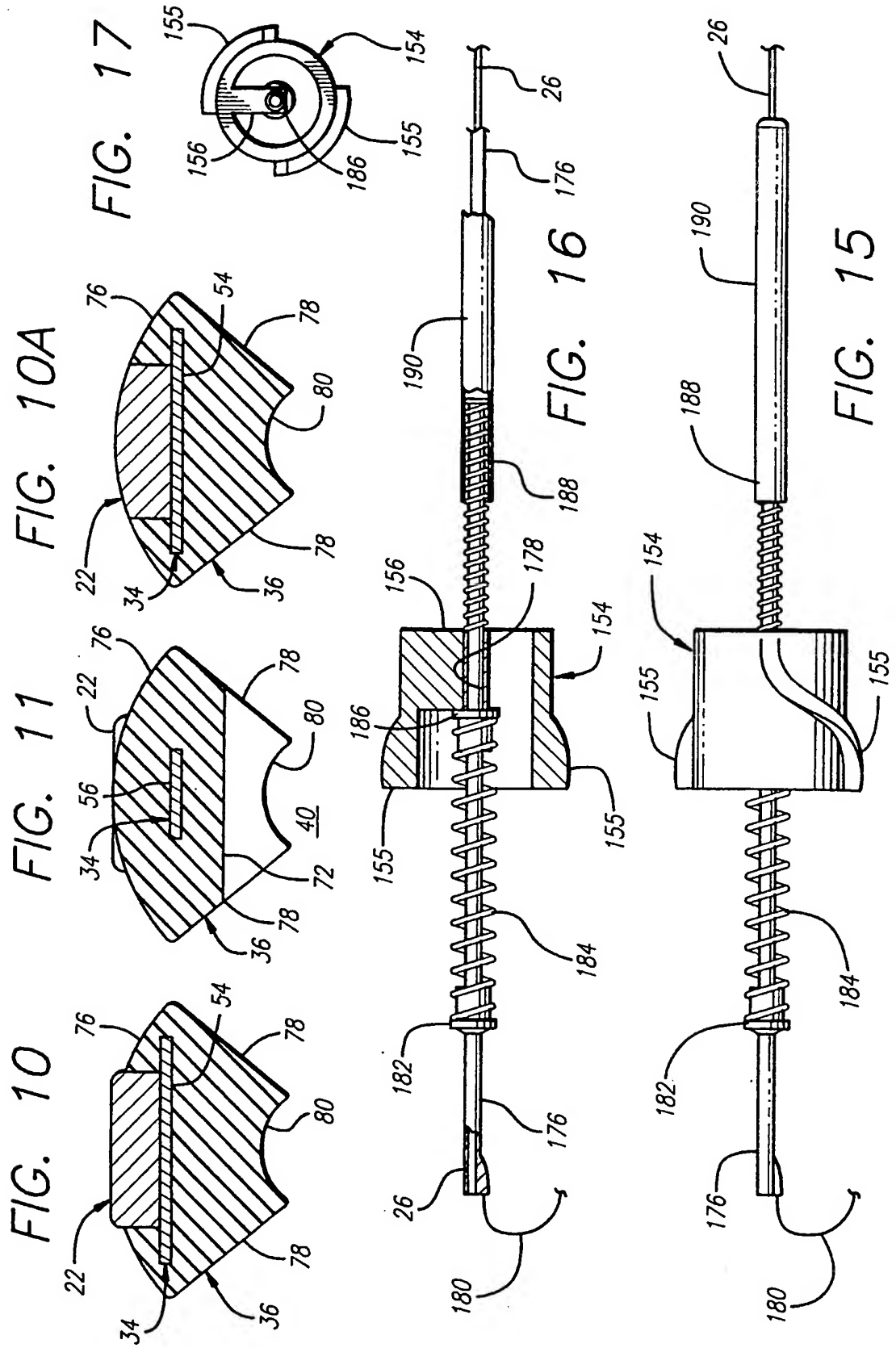


FIG. 10
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FIG. 12

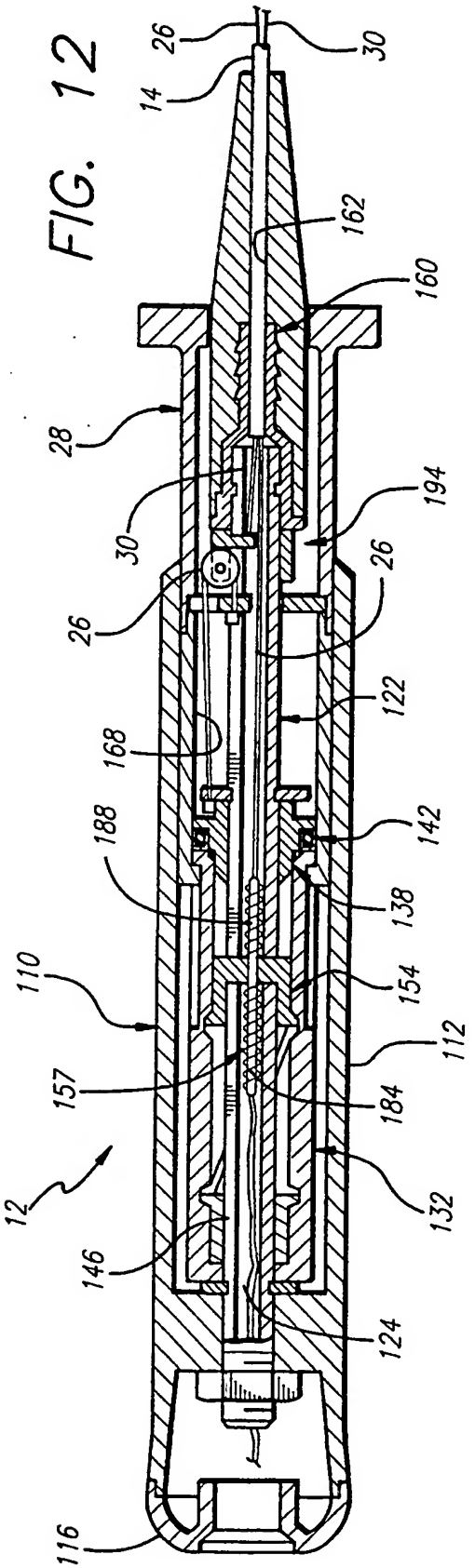
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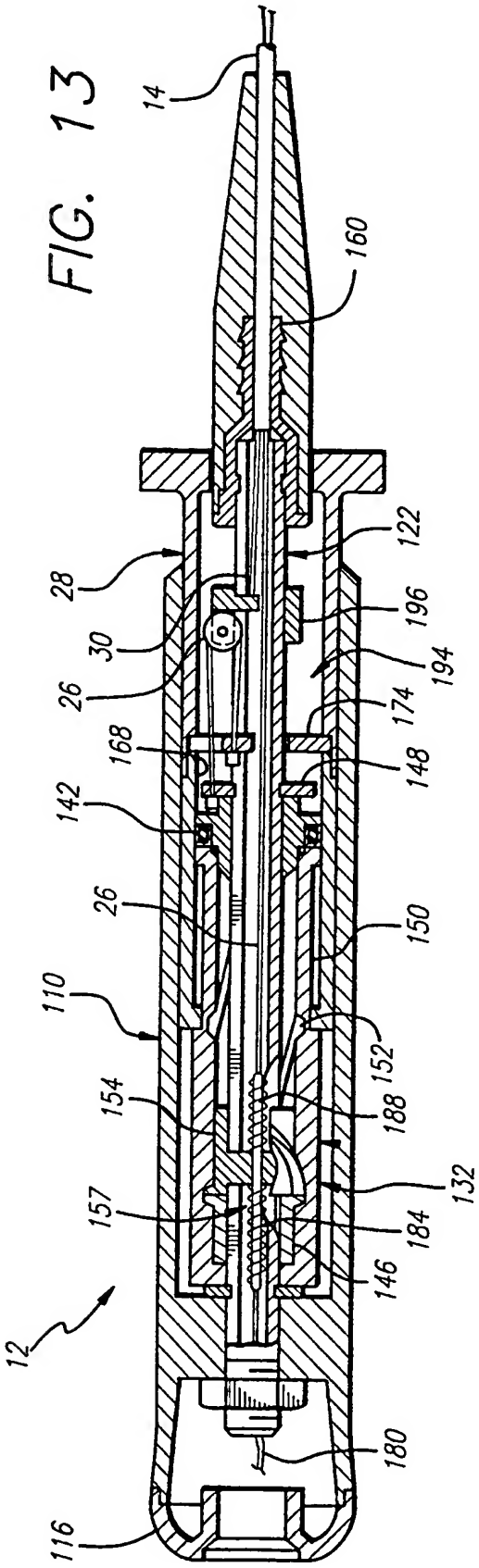
FIG. 13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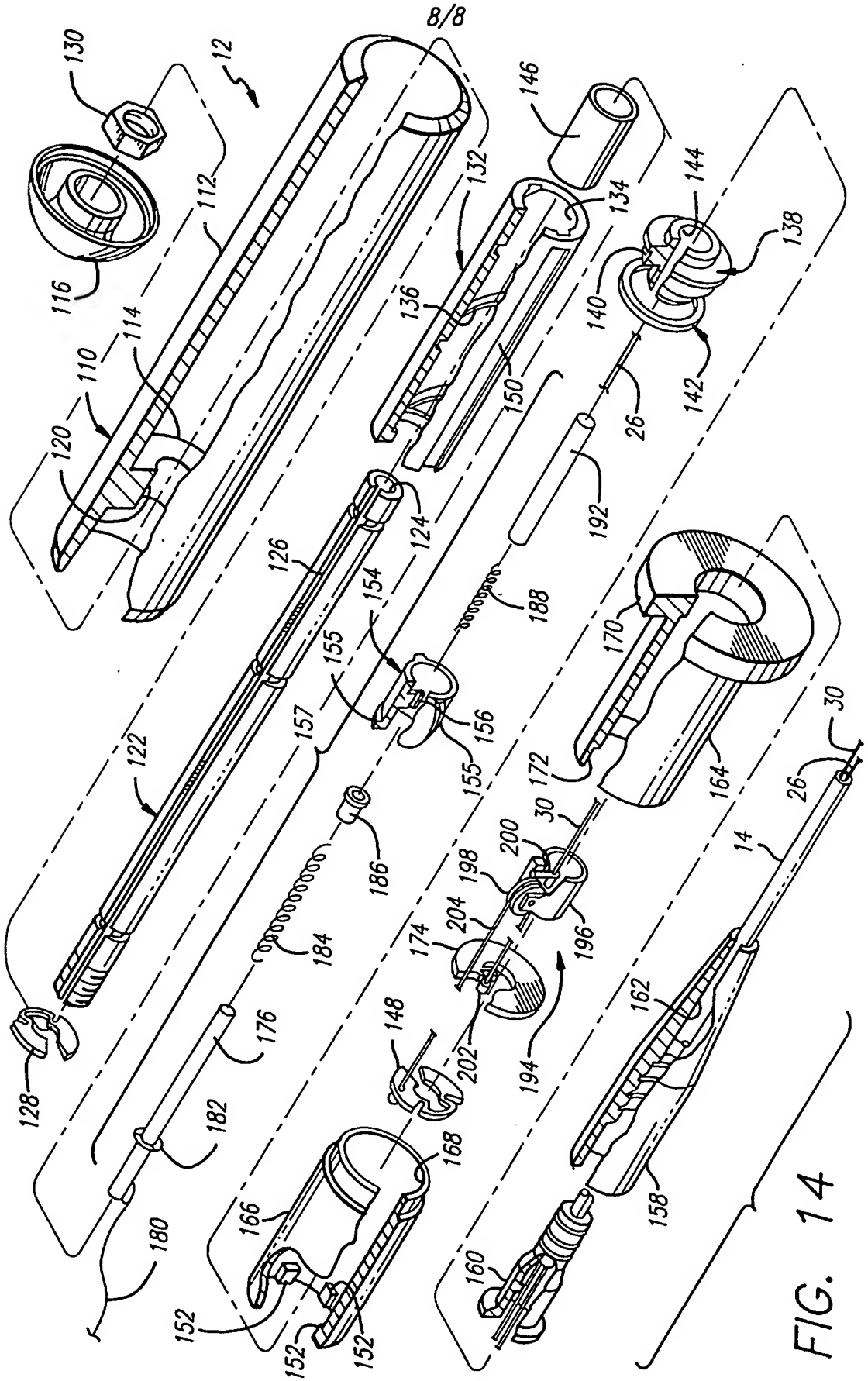
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FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/06032

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) . :A61B 5/042
US CL :128/642; 606/41; 607/122
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/639, 642; 604/105, 107; 606/41; 607/122, 126

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,660,571 (HESS ET AL.) 28 April 1987, see entire document.	1-7
Y	US, A, 5,275,610 (EBERBACH) 04 January 1994, see entire document.	1, 7
Y	US, A, 5,313,943 (HOUSER ET AL.) 24 May 1994, see entire document.	5, 6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
05 JUNE 1996	23 JUL 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer HERMAN J. ROBINSON Telephone No. (703) 308-2909

Form PCT/ISA/210 (second sheet)(July 1992)★